Import Instructions – European Union member states, European Free Trade Association Member States, Greenland and the Faroe Islands where they align with EU sanitary and phytosanitary rules

You need to enclose the following:

1-VAT exemption certificate, signed and dated in ink – available on request from Dr Binks

The remaining documents are enclosed in this pdf:

- 2-Commercial invoice, signed and dated by shipper in ink with weight of parcel added 3-Generic import licence
- 4-Checklist

5-I also highly recommend a veterinarian letter, signed in ink on headed paper, stating the following:

To whom it may concern:

I confirm that the enclosed samples are not derived from animals known or suspected to be infected with a pathogen which causes a disease that is notifiable in England, Scotland, Wales or the European Union, and is listed in Schedule 1 of The Specified Animal Pathogens Order 2008, The Specified Pathogens (Scotland) Order 2009 or The Specified Pathogens (Wales) Order 2008, and do not originate from animals in a premises, region or zone of a country that is subject to official restrictions due to a notifiable disease to which the animals from which the products are derived are susceptible.

Please ensure all parcels are UN3373 compliant packaged (instructions at end of pdf).

ALL DOCUMENTS MUST BE ENCLOSED IN A CLEAR PLASTIC WALLET ON THE EXTERIOR OF THE PARCEL.





COMMERCIAL INVOICE

VAT NUMBER GB125506730

EORI NUMBER GB125506730065

DATE / /2025

SENDER ADDRESS

NAME OF VET

Name and address of hospital

RECEIVER ADDRESS
Dr Sophie Binks
Oxford Autoimmune Neurology Group
Nuffield Department of Clinical Neurosciences
Level 6 - West Wing
John Radcliffe Hospital
Oxford
OX3 9DU

OX3 UK

Tel: 01865 (2)34829

PACKAGE CONTENTS

Blood and serum samples from a [insert country of origin here] domestic cat, non-infective, non-toxic

THE EXPORTER OF THE PRODUCTS COVERED BY THIS

DOCUMENT (EORI NUMBER) DECLARES THAT,

EXCEPT WHERE OTHER WISE CLEARLY INDICATED

THESE PRODUCTS ARE OF UK PREFERENTIAL ORIGIN

AND THAT ALSO

i. the products are not derived from animals known or suspected to be infected with a pathogen which causes a notifiable disease to which the animals from which the products are derived are susceptible according to retained European Regulations or the Animal Health Regulations of the exporting country; and

ii. the products do not originate from animals in a premises or region or zone of a country that is subject to official restrictions due to a notifiable disease to which the animals are susceptible according to European or other National Animal Health Regulations.

iii. These products are category 1 as defined in Articles 8, 9 or 10 of Regulation (EC)No 1069/2009

Nominal £1 HS CODE 30029030

TOTAL WEIGHT

TERMS OF CARRIAGE C.P.T

EURO 1/T2L

THIS INVOICE SHOWS THE FULL VALUE OF THE ARTICLES AND NO OTHER

INVOICE WILL BE ISSUED

SIGNED

PRINT

NAME OF VET

Department for Environment, Food and Rural Affairs

Scottish Government

Welsh Government

Commission Regulation (EU) 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive ("Regulation 142/2011")

The Trade in Animals and Related Products Regulations 2011

The Trade in Animals and Related Products (Scotland) Regulations 2012

The Trade in Animals and Related Products (Wales) Regulations 2011

The Animal By-products (Enforcement) (England) Regulations 2013

The Animal By-Products (Enforcement) (Scotland) Regulations 2013

The Animal By-Products (Enforcement) (Wales) Regulations 2014

General authorisation to import research and diagnostic samples (IMP/GEN/2024/13)

Date issued: 16 December 2024

Valid until further notice or unless revoked by the Secretary of State, Scottish ministers, Welsh ministers or both

Details

You must comply with the conditions of this general authorisation if you import any of the following products into Great Britain:

research and diagnostic samples

Where all the following apply:

- they consist of animal by-products and derived products intended for only the following purposes: examination in the context of diagnostic activities or analysis for the promotion of progress in science and technology, in the context of educational or research activities.
- they are not intended for re-sale

Originating from:

- European Union member states
- European Free Trade Association member states
- Greenland and the Faroe Islands where they align with EU sanitary and phytosanitary rules

Page 1 of 6 Authorisation no: IMP/GEN/2024/13

Arriving at (point of entry):

• any point of entry in Great Britain

Authorisation issued on 16 December 2024 under Article 27 of Regulation (EU) 142/2011 on behalf of the:

Secretary of State for Environment, Food and Rural Affairs by:

Clare Parnham, officer of the Department for Environment, Food and Rural Affairs

Clare Parler Signature:

Official stamp:

Signature.

Scottish ministers by:

Jesus Gallego, a member of staff of the Scottish ministers

Jenus Cally

Signature:

Welsh ministers by:

Dr Richard Irvine MRCVS, Chief Veterinary Officer for Wales, a member of staff of the Welsh ministers

Signature:

Conditions attached to this authorisation

1. Any breach of these conditions must be reported to the Animal and Plant Health Agency (APHA) Centre for International Trade, Carlisle.

Packaging

- 2. The material must be packed in leak-proof sealed containers.
- 3. All inner and outer packaging must be swabbed with suitable disinfectant before leaving the exporting address.
- 4. The packaging must be clearly labelled to indicate the nature of the product, that it is intended for use in research and that it is not for human or animal consumption.
- 5. Irrespective of the mode of transport, all specimens must be packaged so that they fully

Page 2 of 6 Authorisation no: IMP/GEN/2024/13

- comply with the requirements of relevant Post Office or International Air Transport Association (IATA) regulations.
- 6. The products must always remain in their original packaging and wrapping until their arrival at the destination.

Storage, use and handling

- 7. The samples, and material derived from the samples, shall be for in vitro use only.
- 8. None of the material this authorisation relates to shall be used for human or animal consumption under any circumstances.
- 9. Any subsequent use of these products for purposes other than those referred to in point 38 of annex 1 of Regulation (EU) No 142/2011, is prohibited.
- 10. Samples must be handled and stored under a containment level which is appropriate to the risks presented by the product. This should be determined by the operator, following a suitable risk assessment, in accordance with The Control of Substances Hazardous to Health Regulations 2002.
- 11. Users shall take all necessary measures to avoid spreading diseases communicable to humans or animals during the handling of the materials under their control, particularly by applying good laboratory practice.
- 12. Unless they are kept for reference purposes or re-dispatched to the third country of origin, research and diagnostic material, products derived from their use and waste shall be disposed of appropriately. This must be done in accordance with The Waste (England and Wales) Regulations 2011 or The Waste (Scotland) Regulations 2012 or Section 1 of Chapter III of Annex XIV Regulation (EU) 142/2011.
- 13. Any transfer of material from the authorised user to any other user must be pre-authorised by APHA.

Transportation

- 14. The consignment must be sent directly from the point of entry into Great Britain to the authorised user at the destination address listed on the commercial document.
- 15. The material must be transported, handled and labelled in accordance with the Animal Byproducts Regulations.
- 16. Before starting operations, the transporter and destination address must be registered or approved (see general note 6) in accordance with the relevant Animal By-Products (Enforcement) Regulations.

Import documentation

- 17. Each consignment must be accompanied by a:
 - copy of this authorisation

Page **3** of **6** Authorisation no: IMP/GEN/2024/13

- commercial documentation (see point 18)
- 18. Each consignment must be accompanied by a commercial document signed by a person with knowledge of, and responsibility for, the relevant parts of the production process. It must be on company letter-headed paper and dated within 2 months of the importation date of each consignment. The document must include the:
 - · description of the product and animal species of origin
 - category of the product (1, 2 or 3) as defined in Articles 8, 9 or 10 of Regulation (EC) No 1069/2009
 - quantity of the product
 - place and country of origin
 - place of dispatch of the product
 - name and address of consignor
 - name and address of the consignee or user, or both

The document should also confirm that the product (see general note 7):

- is not derived from animals known or suspected to be infected with a pathogen which
 causes a disease that is notifiable in England, Scotland, Wales or the European Union,
 and is listed in Schedule 1 of The Specified Animal Pathogens Order 2008, The
 Specified Pathogens (Scotland) Order 2009 or The Specified Pathogens (Wales)
 Order 2008
- does not originate from animals in a premises, region or zone of a country that is subject to official restrictions due to a notifiable disease to which the animals from which the products are derived are susceptible

General notes

- 1. References to European Union (EU) legislation within this document are references to direct EU legislation which has been assimilated in Great Britain (assimilated direct legislation), as defined in the Retained EU Law (Revocation and Reform) Act 2023. This can be viewed on the UK legislation website (legislation.gov.uk).
- 2. This authorisation is granted under animal and public health import legislation. It gives no exemption from any prohibition, regulation or restriction imposed by any other government department or agency.
- 3. Import conditions in general authorisations can be subject to change and importers are advised to check they are using the current version.
- 4. In accordance with Annex VIII, Chapter III, point 5 of Regulation (EU) No 142/2011, all records and related documentation associated with material imported under this authorisation must be kept for a minimum of 24 months for presentation to the competent authority.
- 5. Any products, or records relating to the product, imported under this authorisation must be provided for inspection if requested by an officer of the Animal and Plant Health Agency or an enforcement authority, at any place nominated by them. The importer or their agent must provide any assistance required by the officer to carry out the inspection. The importer will be

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- responsible for meeting any costs related to carrying out the inspection.
- 6. For information on registration or approval, visit https://www.gov.uk/animal-by-product-categories-site-approval-hygiene-and-disposal#getting-your-site-approved-or-registered
- 7. In Great Britain, notifiable diseases are animal diseases that you're legally obliged to report to the Animal and Plant Health Agency, even if you only suspect that an animal may be affected. Notifiable diseases are named in Section 88 of the Animal Health Act 1981, an Order made under that Act or are diseases that are required to be notified in accordance with assimilated EU legislation. For further information on notifiable diseases in Scotland, England and Wales, visit:
 - England: https://www.gov.uk/government/collections/notifiable-diseases-in-animals
 - Scotland: https://www.gov.scot/collections/animal-diseases-notifiable-and-non-notifiable-diseases/
 - Wales: https://www.gov.wales/notifiable-diseases

In the EU, a notifiable disease is any disease that is required by law to be reported to government authorities. The diseases are categorised in accordance with Regulation (EU) 2016/429 (known as Animal Health Law) and Commission Implementing Regulation (EU) 2018/1882.

Caution

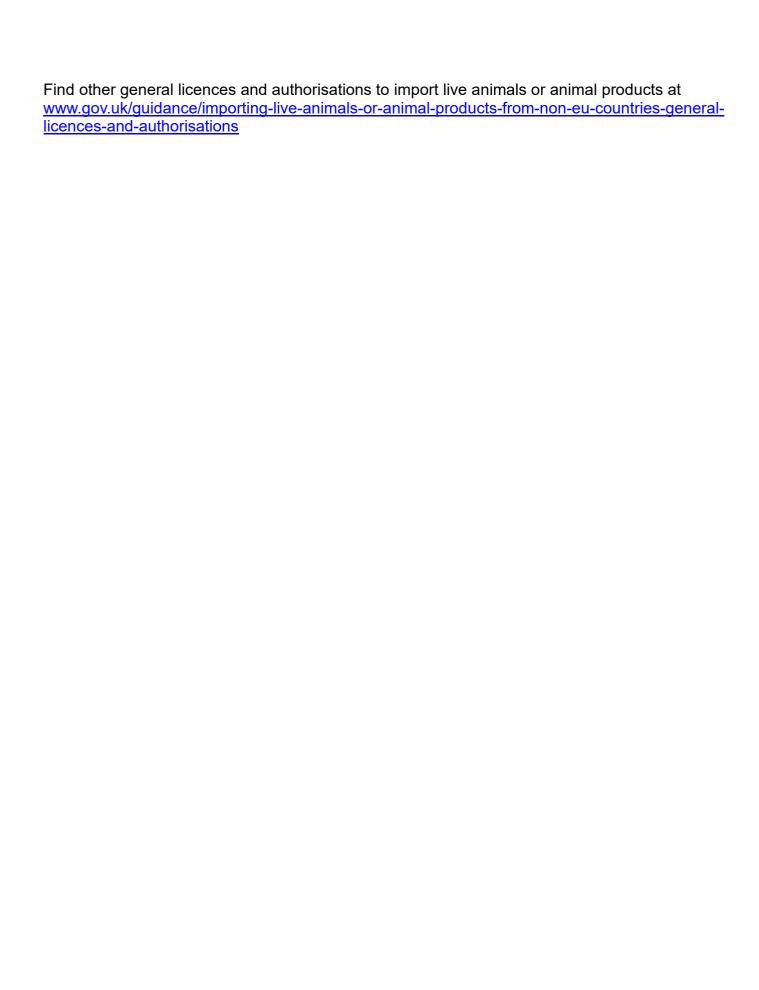
- 1. It is the responsibility of the importer to ensure that any import covered by this authorisation complies with the terms and conditions as set out.
- 2. Any breach of any conditions attached to this authorisation will constitute an offence against regulation 39 of The Trade in Animals and Related Products Regulations 2011, The Trade in Animals and Related Products (Wales) Regulations 2011, regulation 33 of The Trade in Animals and Related Products (Scotland) Regulations 2012, or regulation 17 of the Animal By-products (Enforcement) (England) Regulations 2013, The Animal By-Products (Enforcement) (Wales) Regulations 2014 or regulation 18 of The Animal By-Products (Enforcement) (Scotland) Regulations 2013.

Contact for further information

Animal and Plant Health Agency (APHA)
Imports Team
Centre for International Trade - Carlisle
Eden Bridge House, Lowther Street
Carlisle
CA3 8DX

Telephone: 03000 200 301 Email: imports@apha.gov.uk

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Inventory form for importation of samples into the UK

This consignment contains the following (delete as applicable):
(a) Description:
Animal species of origin: DOMESTIC CAT
Material: BLOOD / SERUM / CSF
(b) The material is Category 1. More information on sample Categories can be found in Regulation (EC) No 1069/2009.
(c) There aresamples with a total weight ofgrams
[Note: net (total) weight including packaging must not exceed 15000g]
(d) Place of origin
Place of dispatch
(e) Name and address of consignor (sender)

I confirm that the enclosed samples are not derived from animals known or suspected to be infected with a pathogen which causes a disease that is notifiable in England, Scotland, Wales or the European Union, and is listed in Schedule 1 of The Specified Animal Pathogens Order 2008, The Specified Pathogens (Scotland) Order 2009 or The Specified Pathogens (Wales) Order 2008, and do not originate from animals in a premises, region or zone of a country that is subject to official restrictions due to a notifiable disease to which the animals from which the products are derived are susceptible

(f) Name and address of consignee (recipient)

Sophie Binks
Nuffield Department of Clinical Neurosciences
Level 6 – West Wing
John Radcliffe Hospital
Oxford
OX3 9DU
UK

Signed _______
Date ______

□ Each individual consignment does not exceed 15kg
□ Samples contained within a leak-proof sealed container
□ All inner and outer packaging swabbed with a suitable disinfectant before leaving the exporting address
☐ All specimens are packaged so that they comply with requirements of Post Office or International Air Transport Association (IATA) regulations
□ The packaging is clearly labelled with the nature of the product , that it is intended for in vitro use for research or diagnostic purposes and that it is not for human or animal consumption
□ Documents for each individual consignment include:
□VAT EXEMPTION CERTIFICATE
□COMMERCIAL INVOICE
□VETERINARIAN LETTER (USA, AUSTRALIA, HONG KONG, SOUTH AFRICA)
☐IMPORT LICENCE (IMP/GEN/2024/13) (EU COUNTRIES); ITIMP25.0215

Check-list





Packaging UN 3373 Shipments

Packaging UN 3373 Shipments

Follow these instructions for packaging, marking, and labeling Biological Substance, Category B (UN 3373) shipments for FedEx Express® services.

Requirements for Biological Substance, Category B (UN 3373) Shipments

This guide outlines the requirements for shipping with FedEx Express. In addition, all shipments must comply with all applicable local, state, and federal laws governing packing, marking, and labeling. Blood, urine, fluids, and other specimens containing or suspected of containing infectious substances must be shipped according to applicable government, International Air Transport Association (IATA), and International Civil Aviation Organization (ICAO) regulations.

Customers who ship Biological Substance, Category B (UN 3373) shipments must comply with local, state, and federal laws governing identification, classification, packaging, and package markings (which may be in label form). FedEx Express strictly adheres to the IATA, ICAO, and U.S. government guidelines for materials categorized as Biological Substance, Category B (UN 3373).

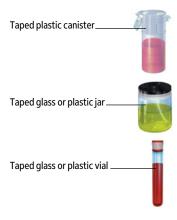
General Packaging Requirements

For Biological Substance, Category B (UN 3373) shipments, cushioning material is required for both liquid and dried specimens. You must include four layers of packaging:

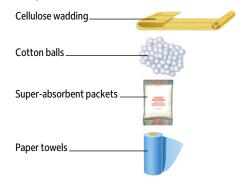
- 1. Primary watertight inner receptacle. Use primary receptacles made of glass, metal, or plastic with a positive means of ensuring a leakproof seal; a skirted stopper or metal crimp seal must be provided; screw caps must be reinforced with adhesive tape. For liquid specimens, the primary receptacle must not contain more than 1 L. For dried specimens, the primary receptacle must not exceed the outer packaging weight limit.
- 2. Absorbent material. Place absorbent material between the primary and secondary receptacles, using enough material to absorb the entire contents of all primary receptacles. Absorbent material is required for Biological Substance, Category B (UN 3373) shipments containing liquids. Acceptable absorbent materials include cellulose wadding, cotton balls, super-absorbent packets, and paper towels.

- 3. Secondary watertight inner receptacle. Use a secondary container that is leakproof for liquid specimens or siftproof for dried specimens. Choose only secondary containers certified by the manufacturer for Biological Substance, Category B (UN 3373) prior to use. Either your primary or secondary receptacle must be able to withstand, without leakage, an internal pressure differential of not less than 95 kPa in the range of -40°C to 55°C (-40°F to 130°F). To prevent contact between multiple fragile primary receptacles, individually wrap or separate them inside the secondary container.
- 4. Sturdy outer packaging. Use rigid outer packaging constructed of corrugated fiberboard, wood, metal, or plastic, or other equally strong material, including cylinders made of such materials and appropriately sized for the contents. Chipboard or paperboard boxes are unacceptable outer packaging. The completed packaging must be of good quality, strong enough to withstand the normal rigors of transportation without loss of contents as a result of vibration, changes in temperature, humidity, or pressure. Limit the total volume for liquid samples to 4 L and the total weight of dried samples to 4 kg per outer container. At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm (4" x 4"). Completed packages must be able to withstand a 4' (1.2-m) impact test. Before sealing the outer packaging, you must make an itemized list of the contents of the package and enclose the list between the secondary packaging and outer packaging.

Acceptable Primary Receptacles



Acceptable Absorbent Materials



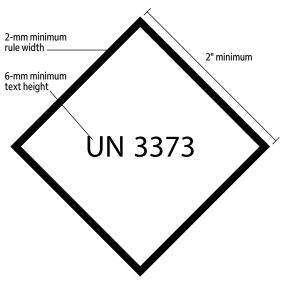
Acceptable Secondary Receptacles



Biological Substance, Category B (UN 3373) Marking Requirements

- Clearly mark "Biological Substance, Category B" in 6-mm-high text on the outer package adjacent to a properly sized UN 3373 diamond-shaped marking. If you prefer, package markings may be in the form of a label.
- If you use any of the following clinical or Temp-Assure® boxes to ship samples classified as Biological Substance, Category B (UN 3373), you must add a properly sized UN 3373 diamond-shaped marking; if you prefer, package markings may be in the form of a label:
 FedEx® Medium Clinical Box; FedEx® Large Clinical Box; Small Cold Box (2–8°) Standard Duration (48 Hours); Medium Cold Box (2–8°) Standard Duration (48 Hours); Medium Cold Box (2–8°) Extended Duration (48 Hours); Large Cold Box (2–8°) Standard Duration (48 Hours); and Large Cold Box (2–8°) Extended Duration (96 Hours).
- If you use the FedEx® UN 3373 Pak, duplicate all required dangerous goods markings on each package inside the overpack. Do not place dry ice inside the pak.
- The name and telephone number of a person responsible must be marked on the package or provided on the airbill.
- The name and address of the shipper and recipient must be marked on the package.

Biological Substance, Category B (UN 3373) Marking Requirements



"Biological Substance, Category B" must appear in 6-mm-high text on the outer package adjacent to a diamond-shaped mark like the one shown here. The UN 3373 marking must be in the form of a square set at an angle of 45 degrees. Each side of the UN 3373 diamond should measure a minimum of 2" (50 mm). The width of the diamond rule line must be a minimum of 2 mm, and the letters and numbers must be at least 6 mm high.

FedEx UN 3373 Packaging Options

For your convenience, we offer the FedEx UN 3373 Pak, the FedEx Medium Clinical Box, and the FedEx Large Clinical Box as packaging options for your Biological Substance, Category B (UN 3373) shipments. We recommend the FedEx UN 3373 Pak for use when the sturdy outer packaging of your properly packaged shipment is smaller than 7" x 4" x 2" (minimum acceptable size).

To help increase your operational efficiencies and clearly identify this type of shipment, the FedEx UN 3373 Pak is preprinted with the required IATA UN 3373 marking, the proper shipping name, and the OVERPACK marking.

The FedEx UN 3373 Pak can only be used to ship Biological Substance, Category B (UN 3373) shipments. If you need an overwrap for exempt clinical and environmental test sample shipments, use the FedEx® Clinical Pak.

To order the FedEx UN 3373 Pak, go to **fedex.com** or call 1.800.GoFedEx 1.800.463.3339.

FedEx UN 3373 Pak



FedEx Large Clinical Box, FedEx Medium Clinical Box





FedEx UN 3373 Packaging Options for Purchase

FedEx offers five cold shipping boxes as part of the FedEx Temp-Assure portfolio of products **for purchase**. These boxes can be used as outer packaging to ship temperature-sensitive specimens designated as Biological Substance, Category B (UN 3373) with FedEx Express services.

Each box includes a chilling unit activated by the shipper and placed in the box with the shipment. The unit continuously evaporates small amounts of water at low pressure, keeping the shipment at 2°C to 8°C for up to 48 or 96 hours,* depending on the packaging option chosen.



^{*}Actual cooling duration varies, depending on external temperatures.

Packaging Restrictions

- Plastic bags and paper envelopes are unacceptable outer containers.
- The FedEx® Envelope, FedEx® Tube, FedEx® Pak, FedEx® Padded Pak, and FedEx boxes, including FedEx brown packaging offered at FedEx shipping locations, are not acceptable as outer containers for Biological Substance, Category B (UN 3373) shipments.
- The FedEx Small Clinical Pak and FedEx Large Clinical Pak cannot be used to ship Biological Substance, Category B (UN 3373) shipments.
- Only shipments classified as Biological Substance, Category B (UN 3373) can be shipped in the FedEx UN 3373 Pak.
- Biological Substance, Category B (UN 3373) shipments that are shipped refrigerated, frozen, on dry ice, or in liquid nitrogen must comply with current IATA and ICAO regulations.

If you have questions about whether your shipments require a biohazard label, consult the Occupational Safety and Health Administration (OSHA) for the applicable regulations.

The FedEx Medium Clinical Box, the FedEx Large Clinical Box, and the following Temp-Assure cold shipping boxes may be used to ship either non-infectious clinical samples or samples classified as Biological Substance, Category B (UN 3373), but they must be properly labeled: Small Cold Box (2–8°) Standard Duration (48 Hours); Medium Cold Box (2–8°) Standard Duration (48 Hours); Medium Cold Box (2–8°) Extended Duration (96 Hours); Large Cold Box (2–8°) Standard Duration (48 Hours); and Large Cold Box (2–8°) Extended Duration (96 Hours). The shipper assumes sole responsibility for compliance with all applicable governmental regulations.

NOTE: Biological Substance, Category B (UN 3373) shipments are accepted at FedEx Express® Drop Box locations in the U.S. and Puerto Rico. Refer to the current online Service Guide, Terms and Conditions, Dangerous Goods section for current limitations on locations that cannot accept UN 3373.

FedEx Packaging Services

FedEx Packaging Services offers package development consultation services. The FedEx Packaging Lab does not test packaging containing Biological Substance, Category B (UN 3373) materials.

Contacts and Resources

- How to Pack guidelines at fedex.com/packaging.
- FedEx portfolio of temperature-controlled solutions at fedex.com/us/temp-assure.
- FedEx Dangerous Goods/Hazardous Materials
 Hotline, 1.800.GoFedEx 1.800.463.3339; press "81"
 or say "dangerous goods," then press "4" for the next
 available dangerous goods agent.
- FedEx Dangerous Goods seminars and job aid at fedex.com/dangerousgoods.

NOTICE:

FedEx Express will refuse to accept packages that do not meet FedEx Express, government, or IATA and ICAO requirements. This brochure is in no way intended to replace requirements mandated by 49CFR and IATA. This is for informational purposes only.